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REMARKS

Reconsideration of the application as amended is requested.

Applicants note with appreciation the Examiner's indication that claims 7, 14, 21, 26, 28, 29, 31, and 37 contain allowable subject matter.

In the Office Action dated December 20, 2004, the specification was objected to for informal matters. The disclosure has been amended to correct to the matters noted by the Examiner.

Claim 11 was objected to for informal matters. "0.003" has been changed to "0.0003" to correct the matter noted by the Examiner.

Claims 5 and 16 were rejected under 35 U.S.C. §112 (second paragraph) as being indefinite. Claim 4 has been amended to recite a "gel layer," such that "gel layer" in claim 5 is now believed to have proper antecedent basis. Claim 16 has also been amended to correct the §112 matter noted by the Examiner.

Claims 1 and 2 were rejected under 35 U.S.C. §102(b) as being anticipated by Berglund et al., U.S. Patent No. 4,310,509. Claims 1 and 6 were rejected under 35 U.S.C. §102(b) as being anticipated by DeBusk et al., U.S. Patent No. 5,628,724. Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Berglund et al. Claims 1, 4 and 5 were rejected under 35 U.S.C. §103(a) as being unpatentable over JP3-2279719 ("Sekisui") in view of Berglund et al. Claims 1, 6, 8, 10 and 11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cartmell et al., U.S. Patent No. 5,762,620, in view of DeBusk et al. Claim 9 was rejected under 35 U.S.C. §103(a) as being unpatentable over DeBusk et al. Claims 12, 13, and 15-17, 20, 23, 24 and 40 were rejected under 35 U.S.C. §103(a) as being unpatentable over GB 2,157,955 ("Ward") in view of Feld et al. Claims 18 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ward in view of Feld et al., and in further view of Gilbert et al., U.S. Patent No. 5,052,381. Claims 25, 27, 30, 32, 33, 36, 38 and 39 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ward in view of Cartmell et al., and DeBusk et al. Claims 34 and 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ward in view of Cartmell et al., DeBusk et al., and Gilbert et al.

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Applicant respectfully submits that all of the pending claims, as amended herein, are patentable over the cited references.

Claim 1 has been amended to recite a transdermally-effective active ingredient secured to the first side of an ultra thin film. Support for this amendment can be found at paragraph [0026] of the present application, and in U.S. Patent No. 6,576,712 which is incorporated by reference into the present application.

Applicants respectfully submit that Berglund '509 does not disclose a transdermally-effective active ingredient as recited in amended claim 1. Rather, Berglund '509 teaches a topical antimicrobial agent such as iodine, chlorhexidine or polyvinylpyrrolidoneiodine (PVP-I). Thus, Berglund discloses a topical wound dressing including an antimicrobial agent to prevent infection. A topical wound dressing is used for a substantially different purpose than a transdermal delivery system for pharmaceutical agents. Accordingly, Berglund '509 does not teach or suggest a transdermal delivery system as recited in claim 1 including an ultra thin polymeric film having a layer of adhesive and a transdermally-effective ingredient secured to the first side of the ultra thin film.

Applicant respectfully submits that there would be no reason to modify the transdermal patch of Sekisui based upon the teachings of Berglund '509 which discloses a topical wound dressing, at least absent knowledge of Applicant's claimed arrangement.

Applicant further notes that Cartmell '620 and DeBusk '724 also teach topical wound dressings, and Applicant can find no teaching or suggestion in the references themselves to provide a transdermally-effective active ingredient as recited in amended claim 1.

Claims 2-11 depend from claim 1, and are therefore believed to be allowable for those reasons set forth above in connection with claim 1.

Furthermore, claim 6 recites that the transdermally-effective active ingredient is contained in an island member. Applicant respectfully submits that there would be no reason to modify the cited references to provide the transdermal device of claim 6, absent knowledge of Applicant's claimed arrangement.

Independent claim 12 has been amended to recite a transdermally-effective pharmacologically-active ingredient secured to a first side of an ultra thin film. Applicant

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submits that GB 2,157,955 (Ward) and Feld U.S. Patent No. 4,643,180 disclose topical wound dressings, and in no way disclose or suggest a transdermal delivery system including a transdermally-effective pharmacologically-active ingredient secured to an ultra thin film as recited in amended claim 12.

In the Office Action, it was stated that "As to the aggressiveness of the first and second adhesives (claims 12 and 15), in order for the dressing to work as intended, the first adhesive must be less aggressive than the first adhesive such that during application, the handles may be removed from the dressing after both the handles and dressing are adhered to the skin. If this we not the case, film dressing would be removed from the skin without the handles being torn off."

Applicant respectfully submits that Ward '955 does not necessarily teach a second adhesive that adheres more aggressively to skin than a first adhesive. The force required to pull apart two items that are adhesively bonded together depends on the aggressiveness of the adhesive and the area to which the adhesive is applied. With reference to Fig. 7 of Ward, the edge margins 7 and 9 are quite narrow, such that adhesive 8 only acts on a very small area between handle 6 and flexible film 3. Because the adhesive 8 is only applied to a very small area, the force required to remove handle 6 could be very low even if adhesive 8 were quite aggressive. Also, the arrangement of Ward appears to permit a user to hold the flexible film 3 near margin 7 against a patient's skin while the handle 6 is removed to thereby prevent removal of the film 3 from the patient, even if adhesive 8 were aggressive. Accordingly, Applicant submits that Ward '955 does not teach a second adhesive that adheres more aggressively than a first adhesive as recited in Claim 12.

Claims 13-24 depend from independent claim 12, and are therefore believed to be allowable for those reasons set forth above in connection with independent claim 12.

Independent claim 25 has been amended to recite a transdermally-effective active ingredient contained in an island member whose dimensions are less extensive than the dimensions of an ultra-thin film. Applicant submits that Ward, Cartmell, and DeBusk all disclose topical wound dressings. Accordingly, the cited references do not teach or suggest a

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transdermal delivery system including a transdermally-effective active ingredient contained in an island member as recited in amended claim 25.

Furthermore, Applicant submits that the cited references do not teach or suggest a second adhesive that adheres more aggressively to skin or mucosal than a first adhesive as recited in amended claim 25. As discussed above, the adhesive 8 of Ward acts on a very small surface area between handle 6 and flexible film 3, such that adhesive 8 could be quite aggressive.

Claims 26-39 depended from claim 25, and are therefore believed to be allowable for those reasons set forth above in connection with claim 25.


Independent claim 40 has been amended to recite the step of providing a transdermally-effective active ingredient secured to a first side of an ultra thin film. Applicant submits that Ward and Feld both disclose topical wound dressings, and in no way teach or suggest a transdermally-effective active ingredient as recited in amended claim 40.

Applicant has made a concerted effort to place the present application in condition for allowance. In the event there are any remaining informalities, the courtesy of a phone call to the undersigned attorney would be appreciated.

Respectfully submitted,

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JSK:kjc



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